

## CLAIMS

1. Disease determination method for determining whether a person has a certain disease or not using a biological sample, comprising,

5        pretreatment process to add an acidic or alkaline solution to the sample and to heat the sample ,

      excitation light irradiation process to irradiate the sample with excitation light and to continuously or intermittently change the wavelength of the excitation light,

10       emission light measurement process to measure the wavelength and intensity of the emission light emitted from the sample in response to the excitation light,

      analyzing and sorting process to detect a specific point in the three-dimensional optical spectrum composed of the excitation light wavelength, emission light wavelength and emission light intensity and to sort or  
15       hierarchize the sample based on the specific point attribute, and

      determination process to determine the presence or absence of the disease or the condition of the disease of the body to which the sample belongs based on the sorting and hierarchization results of the sample.

20       2. The disease determination method according to claim 1, wherein a specific point attribute is determined by at least one of the parameters, including wavelength coordinates of said specific point, number of the specific points, intensity of said emission light of the specific point, rate of change in the emission light intensity on the periphery of the specific point and the three-dimensional optical spectrum shape in said analyzing and sorting process.

25       3. The disease determination method according to claims 1 or 2, wherein urine is used as said sample.

4. The disease determination method according to any one of claims 1 to 3, wherein fluorescence is measured as said emission light.

5. The disease determination method according to any one of claims 1 to 4, wherein

5       the light having a wavelength in a range of 200-900nm as said excitation light in said excitation light irradiation process and

      fluorescence having a wavelength in a range of 200-900nm as said emission light in said emission light measurement process.

6. The disease determination method according to any one of claims 1 to 5, wherein an acidity adjustment process to adjust acidity of said sample is further included after said pretreatment process is performed.

7. The disease determination method according to claim 6, wherein acidity of said sample is arbitrarily selected from acidic, alkaline, neutral or almost neutral and an acid, alkali or buffer is added to the sample to achieve the acidity selected during said acidity adjustment process.

8. The disease determination method according to claim 7, wherein the acidity of said sample is maintained in alkaline during said acidity adjustment process.

9. The disease determination method according to any one of claims 1 to 8, wherein said specific point is determined by a relative maximum peak of the intensity of said emission light of said three-dimensional optical spectrum in said analyzing and sorting process.

10. The disease determination method according to claim 9, wherein specific point detection maps consisting of a numerical matrix, contour map or vector diagram on said three-dimensional coordinate system are prepared and said specific point is detected based on the specific point detection map in said

analyzing and sorting process.

11. The disease determination method according to any one of claims  
1 to 10, wherein the specific point attribute of said sample subject for the  
determination and the known specific point attributes detected in advance  
5 using the standard samples from the bodies having a known specific type of  
disease are compared and the sample is sorted according to the comparison  
results in said analyzing and sorting process.

12. The disease determination method according to claim 11, wherein  
a standard data generation process is included to generate said known specific  
10 point attributes based on the comparison results of the specific point attribute  
detected using the standard samples from the healthy bodies with the specific  
point attribute detected using the standard samples from the bodies having a  
known specific type of disease.

13. The disease determination method according to any one of claims  
15 1 to 12, wherein said disease is a malignant tumor.

14. Data generation method for disease determination for generating  
data for disease determination using a biological sample obtained from the  
subject, comprising;

20 pretreatment process to add an acidic or alkaline solution to the  
sample and to heat the sample ,

excitation light irradiation process to irradiate the sample with the  
excitation light and to continuously or intermittently change the wavelength of  
the excitation light,

25 emission light measurement process to measure the wavelength and  
intensity of the emission light emitted from the sample in response to the  
excitation light, and

analyzing and sorting process to detect a specific point in the three-dimensional optical spectrum composed of the excitation light wavelength, emission light wavelength and emission light intensity and to sort or hierarchize the sample based on the specific point attribute.

5           15. The data generation method for disease determination according to claim 14, wherein a specific point attribute is determined by at least one of the parameters, including wavelength coordinates of said specific point, number of the specific points, intensity of said emission light of the specific point, rate of change in the emission light intensity on the periphery of the  
10           specific point and said three-dimensional optical spectrum shape in said analyzing and sorting process.

16. The data generation method for disease determination according to claims 14 or 15, wherein urine is used as said sample.

15           17. The data generation method for disease determination according to any one of claims 14 to 16, wherein fluorescence is measured as said emission light.

18. The data generation method for disease determination according to any one of claims 14 to 17, wherein

20           the light having a wavelength in a range of 200-900nm as said excitation light in said excitation light irradiation process and

fluorescence having a wavelength in a range of 200-900nm as said emission light in said emission light measurement process.

25           19. The data generation method for disease determination according to any one of claims 14 to 18, wherein the acidity adjustment process to adjust acidity of said sample is further included after said pretreatment process is performed.

20. The data generation method for disease determination according to claim 19, wherein acidity of said sample is arbitrarily selected from acidic, alkaline, neutral or almost neutral and an acid, alkali or buffer is added to the sample to achieve the acidity selected during said acidity adjustment process.

5           21. The data generation method for disease determination according to claim 20, wherein the acidity of said sample is maintained in alkaline during said acidity adjustment process.

22. The data generation method for disease determination according to any one of claims 14 to 21, wherein said specific point is at least one of a  
10           relative maximum peak, a relative minimum peak and a point having  $1/n$  of the intensity of the relative maximum peak ( $n>1$ ) of said emission light in said three-dimensional optical spectrum in said analyzing and sorting process.

23. The data generation method for disease determination according to claim 22, wherein specific point detection maps consisting of a numerical  
15           matrix, contour map or vector diagram on said three-dimensional coordinate system are prepared and said specific point is detected based on the specific point detection map in said analyzing and sorting process.

24. The data generation method for disease determination according to any one of claims 14 to 23, wherein the specific point attribute of said  
20           sample subject for the examination and the known specific point attributes detected in advance using the standard samples from the bodies having a known specific type of disease are compared and the sample is sorted according to the comparison results in said analyzing and sorting process.

25. The data generation method for disease determination according to claim 24, wherein the standard data generation process is included to  
25           generate said known specific point attributes based on the comparison results

of the specific point attribute detected using the standard samples from the healthy bodies with the specific point attribute detected using the standard samples from the bodies having a known specific type of disease.

5           26. The data generation method for disease determination according to any one of claims 14 to 25, wherein said disease is a malignant tumor.

27. The data generation system for disease determination for generating disease determination data by analyzing the sample collected from the body of the subject, comprising;

10           excitation light irradiation means to irradiate the sample with the excitation light and to continuously or intermittently change the wavelength of the excitation light,

          emission light measurement means to measure the wavelength and intensity of the emission light emitted from the sample in response to the excitation light, and

15           analyzing and sorting means to detect a specific point in the three-dimensional optical spectrum composed of the excitation light wavelength, emission light wavelength and emission light intensity and to sort or hierarchize the sample based on the specific point attribute to generate sorting data for disease determination.

20           28. The data generation system for disease determination according to claim 27, wherein a specific point attribute is determined by at least one of the parameters, including wavelength coordinates of said specific point, number of the specific points, intensity of said emission light of the specific point, rate of change in the emission light intensity on the periphery of the specific point  
25           and said three-dimensional optical spectrum shape in said analyzing and sorting means.

29. The data generation system for disease determination according to any one of claims 27 to 28, wherein

the light having a wavelength in a range of 200-900nm as said excitation light in said excitation light irradiation means and

5 fluorescence having a wavelength in a range of 200-900nm as said emission light in said emission light measurement means.

30. The data generation system for disease determination according to any one of claims 27 to 29, wherein said specific point is at least one of a relative maximum peak, a relative minimum peak and a point having  $1/n$  of the intensity of the relative maximum peak ( $n>1$ ) of said emission light in said  
10 three-dimensional optical spectrum in said analyzing and sorting means.

31. The data generation system for disease determination according to any one of claims 27 to 30, comprising a storage means that the known specific point attributes are stored in advance, wherein said analyzing and  
15 sorting means compares the known specific point attributes stored in said storage means and the specific point attribute of the samples obtained from said subject and sorts said sample based on the comparison results.

32. The data generation system for disease determination according to claim 31, wherein standard data generation means is included to generate said  
20 known specific point attributes based on the comparison results of the specific point attribute detected using the standard samples from the healthy bodies with the specific point attribute detected using the standard samples collected from the bodies having a known specific type of disease.